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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,792	06/19/2001	Carol T. Schembri	10010342-1	4369

7590 10-06/2003

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

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DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,792

Applicant(s)

SCHEMBRI

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-36 is/are pending in the application.
- 4a) Of the above claim(s) 16-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3-10, 15 and 33-36 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 6) <input type="checkbox"/> Other: |

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, drawn to an array chamber, classified in class 422, subclass 102.
 - II. Claims 3-15, 33-36, drawn to an array chamber, classified in class 422, subclass 102.
 - III. Claims 16-18, drawn to a first method, classified in class 436, subclass 174.
 - IV. Claims 19-32, drawn to a second method, classified in class 436, subclass 174.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the functional limitations of Group I, i.e., the first and second positions where a film is and is not retained by surface tension. The subcombination has separate utility such as staining microscope slides.
3. Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and

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(2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require that the array face a surface or adjust the spacing between the array and the surface. The subcombination has separate utility such as array hybridization outside of a chamber.

4. Inventions [II, IV] and [I, II] are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used for staining slides.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Bret Field on December 12, 2002 a provisional election was made with traverse to prosecute the invention of group II, claims 3-15, 33-36,. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 3-4, 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Pay.

Pay teaches a chamber with bottom 18 and lid 62. Port 56a permits fluid introduction. Means 70, 74 for adjusting the positioning of a membrane with respect to the chamber bottom are provided. It is the examiner's position that the membrane is

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structurally capable of supporting an array. Additionally, it is the examiner's position that cells will inherently attach to the membrane and that cells attached to the membrane constitute the instant array.

12. Claims 5, 7-10, 15, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pay.

Pay fails to teach mixing, temperature control or a station (defined on page 13 of the instant application as a housing for holding plural chambers).

Mahe teaches in an incubator with temperature control and agitation for growing cells.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the chamber of Pay in an incubator (instant station) having temperature control and agitation in order to culture samples under optimal temperature and agitation to increase mass transfer as was known in the art as taught by Mahe. With respect to claim 5, it would have been obvious to attach the lid by any known means for the convenience of not losing the lid.

13. Claims 3-4, 6, 15, 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al (5744096).

Jones teaches a chamber 10 with base 12 and lid 14. Detection zone 34 is an absorbent material having immunoreagents immobilized thereon (col. 4, lines 49-62, col. 8, lines line 9). Adjustable spacers 16 are provided for adjusting the position of the detection zone relative to the base. Fluid ports having wicking materials 24, 28 permit introduction of liquid. The chamber is inserted in a cassette reader (instant station); see

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bridge col. 2-3. Movement of the lid with respect to the base provides an automated system of fluid transfer. With respect to claim 6, in that the spacers are made of gasket-type material and the lid is forced into abutment with them, it is the examiner's position a seal is inherently formed.

14. Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is an examiner's statement of reasons for allowance: The prior art fails to teach or suggest incorporating the claimed features.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

17. Smyczek teaches an adjustable volume hybridization chamber. Although inert filters are used to separate array containing filters, it is the examiner's position that the inert filters do not constitute an adjustable spacing element because each filter is a fixed, not adjustable, width.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-

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4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml